DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 29, 2014

Oehm und Rehbein GmbH
% Daniel Kamm, P.E.
Principal Engineer (Kamm & Associates)
8870 Ravello Ct
NAPLES, FL 34114

Re: K141440
Trade/Device Name: dicomPACS DX-R with flat panel
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-ray System
Regulatory Class: II
Product Code: MQB
Dated: May 29, 2014
Received: June 2, 2014

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M Morris
Division Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141440

Device Name
dicomPACS DX-R with flat panel

Indications for Use *(Describe)*
The dicompacs dx-r with flat panel digital imaging system is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary K140551

Submission Correspondent:	Oehm und Rehbein GmbH Contact: Franziska Günther Phone: (49) 381 36 600 500 Email: franziska.guenther@or-technology.com
Establishment Registration Number:	3006542593
Submission Sponsor:	Oehm und Rehbein GmbH Neptunallee 7c 18057 Rostock GERMANY Phone: (49) 381 36 600 500 Fax: (49) 381 36 600 555
Date summary prepared:	May 23, 2014
Device trade name:	***dicom****PACS*®***DX-R*** with flat panel
Device common name:	Solid State X-ray Imager (Flat Panel/Digital Imager)
Classification:	Class II
Product codes:	MQB at 21 CFR Part 892.1680 LLZ at 21 CFR Part 892.2050
Predicate devices:	K131211, **dicom**PACS®DX-R; Oehm und Rehbein GmbH.
Description of the device:	The ***dicom****PACS*®***DX-R*** with flat panel digital imaging system consists of two components, the ***dicom****PACS*®***DX-R*** software for viewing captured images on a Windows based computer, and one of three solid state X-ray imaging devices: Thales Pixium Portable 2430 EZ (wireless), Thales Pixium Portable 3543 EZ (wireless), or the Perkin Elmer 4336 XRpad (also wireless). The system will display high quality images in less than five seconds over a wide range of X-ray dose settings. The software has the following characteristics: The ***dicom****PACS*® ***DX-R*** software runs on an off-the shelf PC which forms the operator console. Images captured with the flat panel digital detector are communicated to the operator console via LAN or WLAN connection, depending on the model and the user's choice. ***dicom****PACS*®***DX-R*** software uses the software API of the panel manufacturers to control the flat panels and to receive and to calibrate image data. The ***dicom****PACS*® ***DX-R*** software is an independent product for the acquisition, processing and optimization of X-ray images (raw images) provided by flat panel (DR) systems or CR systems. In general, such software is also called „console software" as it is installed on the so-called „console PC" of the imaging device. ***dicom****PACS*® ***DX-R*** carries out the image processing of the raw images provided by the particular device and provides the radiographer / X-ray assistant with optimum workflow for their work. The key difference between the modified device and our predicate device is the panels are wireless, Wi-Fi.
X-Ray Generators Supported	**Manufacturer** Sedecal, Spain Stadler, Swizerland Röntgenwerk Bochum, Germany CPI, Canada EMD Technologies Control-X, Hungary Shimadzu, Japan **Product Name** SHF and RST types 8X Series Editor HFe401 - 801 Indico100, CMP 200 DR EPS 45-80

Indications for Use	The ***dicom****PACS*® ***DX-R*** with flat panel digital imaging system is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.
Substantial equivalence to predicate devices:	All three receptor panels are identical in structure and share nearly identical Indications for Use. The included software offers the same functions as previously cleared in our software K131211. All panels share similar technical parameters as well as the same materials and conversion technique. All panels have been previously cleared by FDA. The key technical difference is that the new panels are wireless, using standard Wi-Fi technology.
Summary of Technological Characteristics	The three new panels have the following specifications; Thales Pixium Portable 2430 EZ (wireless) 24 x 30 cm, 148 µm pixels Thales Pixium Portable 3543 EZ (wireless) 35 x 43 cm, 148 µm pixels Perkin Elmer 4336 XRpad (wireless) : 35 × 43 cm, 100 µm pixels All use standard Wi-Fi communications and have wired Ethernet available.
Summary of Findings from Non-Clinical Testing	Electrical safety and EMC testing was conducted by the respective panel manufacturers in compliance with IEC 60601-1 and IEC 60601-1-2. Software validation and risk analysis was conducted in compliance with FDA guidance documents. The suppliers of the respective panels performed MTF, DQE, linearity, and resolution measurements. Wireless coexistence is assured via use of standard 802.11(n). Wireless communication technology was chosen with the FDA wireless guidance document taken into consideration.
Summary of Findings from Review of Clinical Images	Images from all three panels were reviewed by a US Board Certified Radiologist The panels produce images that are clinically acceptable. The images are of excellent quality, high resolution and are comparable to or better than the images from the predicate devices. A clinical study as described in the FDA Guidance Document Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices Document issued on: August 6, 1999 was conducted successfully.
Conclusion:	There are no significant differences between the ***dicom****PACS*® ***DX-R*** with flat panel digital imaging system and the predicate devices and therefore, ***dicom****PACS*® ***DX-R*** with flat panel does not raise any questions regarding safety and effectiveness. The ***dicom****PACS*® ***DX-R*** with flat panel, as designed, is as safe and effective as the predicate devices, and the device is determined to be substantially equivalent to the referenced predicate devices currently on the market.